

REMARKS

The Claim Rejections under 35 USC § 112

The Office Action has not carried its burden in establishing lack of enablement. No factual basis or reasoning has been provided in this rejection at all.

For example, even the claims are not correctly cited or discussed. At the bottom of page 3, the allegation is that the claims include prophylaxis of edema, cardiac enlargement, body fluid retention and hydrothorax. However, claim 3 (the claim rejected) is directed to the prophylaxis or protection of human skin against wrinkling. Also, the middle of page 3 refers to claim 17. Claim 17 is not part of this rejection.

See *In re Wright*, 27 USPQ2d 1510 (Fed. Cir. 1993) holding that:

When rejecting a claim under the enablement requirement of section 112, the **PTO bears an initial burden** of setting forth a **reasonable explanation** as to why it believes that the scope of protection provided by that claim is not adequately enabled by the description of the invention provided in the specification of the application; this includes, of course, **providing sufficient reasons for doubting any assertions** in the specification as to the scope of enablement.
(Emphasis added.)

This initial burden has not been met by the Office Action, e.g., there is no reasonable explanation and no sufficient reason for doubting any assertions have been provided, and as such, the rejection is improper for at least this reason.

Nevertheless, the applicants address the rejection as if it was a proper rejection.

The Office Action admits that there are a number of working examples for production of compositions that treat wrinkling, but that applicant has failed to enable the prophylaxis or prevention. The examples however teach/demonstrate the effectiveness of the claimed compounds in prevention.

Example 1, demonstrates that "harmful influences and damage to skin cells and collagen fibres owing to the expression of matrix metalloproteinases and pro-inflammatory genes [are] avoided" by "inhibit[ing] the UV A induced release of the second messenger." This is achieved by the pre-treatment of normal human keratinocytes with a compound of the present claims prior to subjection to a UV-A radiation dose of 30 J/cm². Thus, treatment prior to radiation avoids (prevents) damage to the skin cells.

As explained on the first page of the application, the "metabolic cascade effected, for example, by UV-induced release of ceramides, which are specific second messengers, results

in increased synthesis of pro-inflammatory proteins and reactive oxygen species which can damage skin cells. This cell damage is an essential influencing factor for skin ageing, in particular premature skin ageing and wrinkling of the human skin.” Thus, the interruption or avoidance of this metabolic cascade, leads to the prevention of wrinkling of the skin, and said interruption or avoidance has been demonstrated by the application.

Example 2A demonstrates that pre-treatment of cells before radiation completely suppresses ceramide formation induced by UVA radiation. See the above again for the role of ceramide formation in the metabolic cascade.

Also see examples 2B, 2C, and 2D, each demonstrating the effect of pre-treatment in various assays.

And even if no prevention would have been demonstrated, which is not required of an applicant in order to provide an enabling disclosure, there is no appropriate reason for the rejection in the Office Action.

A specification disclosure which “contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as in compliance with the enabling requirement of the first paragraph of § 112 unless there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support.” (Emphasis added.) *In re Marzocchi*, 169 U.S.P.Q. 367, 369 (1971). “The PTO must have adequate support for its challenge to the credibility of applicant’s statements of utility”. (The quoted statement was made in the context of enablement, i.e., the how-to-use requirement of the first paragraph of section 112.) See also *In re Bundy*, 209 USPQ 48 (1981). The only relevant concern of the Patent Office should be over the truth of assertions relating to enablement. The first paragraph of section 112 requires nothing more than objective enablement. See *In re Marzocchi*, *supra*.

The Examiner has not established any basis to doubt objective enablement. The Examiner has also provided no support for establishing that one of ordinary skill would doubt the objective truth of the asserted utility, which is enabled by the specification. The enablement rejections by the Examiner are thus unfounded. The rejection therefore was improper under *In re Marzocchi*.

The claim rejected is directed to the prophylaxis or protection of human skin against wrinkling, which in view of the state of the art is not objectively doubtable. See, e.g., the numerous products on the market regarding skin wrinkling. Thus, there is no basis for the

rejection as there is no indication that one of ordinary skill in the art would have questioned the effect of the drugs in view of the disclosure and the state of the art. See *Rasmusson v. Smithkline Beecham Co.*, 75 USPQ2d 1297 (Fed. Cir. 2005).

Reconsideration is respectfully and courteously requested.

The Claim Rejections under 35 USC § 103

There is no merit to the rejection as none of the prior art compounds cited by the Office Action is within the scope of the present claims. The compounds of Mohammad, as alleged are imidazol compounds. However, the compounds of the present claims are dihydro imidazol compounds. Moreover, the Mohammad's compounds have a $-C=C-CO_2H$ substituent, which is not an option for the compounds of the present claims.

Withdrawn Claims

Claims 12, 14, 15 and 20 were previously amended to be within the scope of the elected matter (they are all dependent on claim 3), yet the Office Action has not treated said claims on the merits. The consideration of these claims is respectfully solicited.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,

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